UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA, *and* Tom Proctor	)	
v.	)	Civil Action No. 4:17-cv-169-ALM-KPJ
Next Health, LLC, Semyon Narosov, and Andrew Hillman	)	

DEFENDANT NEXT HEALTH, LLC'S
MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT

Defendant Next Health, LLC ("Next Health") moves to dismiss this False Claims Act ("FCA") action pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6) for failure to plead fraud with particularity and pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6) for failure to state a plausible claim. Next Health requests that the Court dismiss the Amended Complaint with prejudice.

I. Statement of Issue

Does Relator's Amended Complaint, which still does not identify a single claim submitted to a government healthcare program ("GHP"), adequately plead Relator's fraud-based claim against Next Health with the particularity required by Federal Rule of Civil Procedure 9(b) and consistent with the requirements of Rules 8(a) and 12(b)(6)?

II. Governing Law

A. Elements of an FCA Claim

To state an actionable claim under the FCA, a relator must sufficiently plead four elements: "(1) [that] 'there was a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused [a GHP] to pay out money or

to forfeit moneys due (*i.e.*, that involved a claim).'" *U.S. ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009); see also, 31 U.S.C. § 3729(a)(1)(A), (B), and (G).

Where, as here, the falsity element of the FCA claim is predicated on violation of the Antikickback Statute, 42 U.S.C.S. § 1320a–7b(b) (the "AKS"), a relator must also adequately plead the underlying AKS violation: "knowing or willful offering to pay, or soliciting, any remuneration to induce the referral of an individual for items or services that may be paid for by a federal health care program." *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 893 (5th Cir. 2013).

B. Rule 9(b) Requirements for FCA Claims in the Fifth Circuit

FCA Relators may satisfy their heightened pleading requirements under Rule 9(b) in two ways: (1) they may "allege the details of an actually submitted false claim," or (2) they may allege "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States ex rel. Grubbs v. Ravikumar Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). This flexibility does not "absolve[] qui tam relators of the heightened pleading requirements under Rule 9(b)." *Nunnally*, 519 F. App'x at 893. A relator who cannot allege the details of an actually submitted false claim, is required "to provide other reliable indications of fraud and to plead a level of detail that demonstrates that an alleged scheme likely resulted in bills submitted for government payment." *Id*.

In the context of FCA allegations based on alleged violations of the AKS, sweeping and conclusory allegations of the existence of violative agreements without detail or particularity are insufficient. *See id.* at 894. The complaint "must provide reliable indicia that there was a kickback provided in turn for the referral of patients. This requires pleading that [the Defendant] knowingly paid remuneration to specific physicians in exchange for referrals." *Id.* To meet this burden,

Relator must identify payments and "reliably indicate" that such compensation "constute[s] 'remuneration' to the physicians" as that term is defined in the AKS. *Id.* Relator must also allege facts that "demonstrate a strong inference that the claims were presented to the Government." *Id.* at 895.

C. Rule 8(a): Stating a Plausible Claim for Relief

To survive a motion to dismiss under Rules 8(a) and 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face," allowing the Court to "draw the reasonable inference that the defendant is liable for the misconduct alleged." *Bell Atlantic Corp.*, 550 U.S. at 570; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft*, 556 U.S. at 668.

Testing a complaint's facial plausibility first requires separating any "well-pleaded facts" from "conclusory statements" and "legal conclusion[s] couched as . . . factual allegation[s]." *Bell Atlantic Corp.*, 550 U.S. at 555. "[C]onclusory" allegations, "formulaic recitation of the elements of a cause of action," "labels and conclusions," "naked assertion[s]," and "conclusory assertions of illegal behavior or intent" must be stripped from the pleading and disregarded. *Ashcroft*, 556 U.S. at 678–680 (citation omitted); *Bell Atlantic Corp.*, 550 U.S. at 555–557. Then, the court must determine whether the remaining well-pleaded factual allegations, if any, are sufficient to pass the plausibility test. Testing plausibility is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Ashcroft*, 556 U.S. at 679. A claim is "plausible" if the well-pleaded facts "raise a right to relief above the speculative level." *Bell Atlantic Corp.*, 550 U.S. at 555. A claim is not plausible when alternative legally appropriate

explanations are likely or "obvious;" in those circumstances, it is not reasonable to infer unlawful behavior. *Id.* at 567.

III. Argument

Relator's Amended Complaint does not cure the deficiencies of his Original Complaint. Relator still does not identify a single allegedly false GHP claim, and the new details in the Amended Complaint "do not offer factual information with sufficient indicia of reliability, and do not demonstrate a strong inference that the claims were presented to the Government in violation of § 3729(a)(1)." *Nunnally*, 519 F. App'x at 895.

Relator's previous filings demonstrate that he has access to thousands of pages of claims and reimbursement data. If his FCA allegations have any merit, it should have been trivial to identify hundreds if not thousands of GHP claims and to include them in the complaint. However, his Amended Complaint, like the Original, does not identify a single allegedly false GHP claim.

Similarly, the Amended Complaint does not present allegations of the "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Grubbs*, 565 F.3d at 190. Instead, Relator has added a myriad of red herrings – factual details that do not lead to FCA liability.

Relator's first substantive addition in the Amended Complaint is Exhibit 1, which consists of several examples of prior approval protocols for therapeutic drug interchange. The inclusion of these agreements does nothing to bolster Relator's allegations because there is nothing illicit about the agreements. Relator claims without providing any factual support that substitutions were made "without consideration of, or adherence to, Federal or State regulations prohibiting such substitutions" but does not identify the "Federal or State regulations" that are allegedly violated. Amended Complaint at ¶ 47. In fact, these prior approvals are contemplated by 22 Tex. Admin.

Code § 291.33(c)(5)[1] and 22 Tex. Admin. Code § 295.13(b)(4).[2] Relator does not actually allege that the agreements included in Exhibit 1 violate the AKS. [3] They clearly do not – none of the agreements included in Exhibit 1 provide for any payment of any sort to any of the providers, and none of the agreements implicate the AKS in any way.

Relator does not allege with particularity any payment that would violate the AKS. Relator now alleges, "upon information and belief," that sixteen identified individuals were "employed by Next Health, LLC as marketers or 'sponsors.'" Amended Complaint at ¶ 46. This new allegation is deficient for three reasons:

(1) Relator fails to plead inducement of GHP referrals with regard to the identified individuals. Relator does not allege that any of the listed individuals actually referred GHP business to any pharmacy as a result of their alleged employment by Next Health. *See Nunnally,* 519 F. App'x at 894 ("Nunnally must provide reliable indicia that there was a kickback provided in turn for the referral of patients. This requires pleading that WCCH knowingly paid remuneration to specific physicians in exchange for referrals."). Relator does not allege that any particular pharmacy that received GHP referrals from the identified individuals or submitted GHP claims as a result of their alleged employment.

(2) Relator fails to plead that the alleged payments constitute "remuneration" as defined by the AKS. Relator alleges an employment relationship between the identified individuals and Next

[1] 22 Tex. Admin. Code § 291.33(c)(5). "A switch [by a pharmacist] to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner."
[2] 22 Tex. Admin. Code § 295.13(b)(4). "Drug therapy management – The performance of specific acts by pharmacists as authorized by a physician through written protocol. Drug therapy management does not include the selection of drug products not prescribed by the physician, unless the drug product is named in the physician initiated protocol or the physician initiated record of deviation from a standing protocol."
[3] Relator alleges generally in paragraph 42 that the Blanket Program violates the AKS but does not allege that the Blanket Agreement does so. It is evident from the Amended Complaint that Relator's theory of AKS liability is based not on the Blanket Agreement which provides for no remuneration, but on the unidentified employment contracts suggested in paragraph 46.

Health, but amounts paid between an employer and employee do not constitute remuneration. 42 CFR § 1001.952(i) states clearly that for AKS purposes, "'remuneration' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer …." As in *Nunnally*, the Amended Complaint fails to meet 9(b) requirements and "is insufficient because it does not allege, nor reliably indicate, that the [alleged compensation] constitute[s] 'remuneration.'" 519 F. App'x at 893 ("This 'example' is insufficient because it does not allege, nor reliably indicate, that the two differing pay scales constitute 'remuneration' to the physicians.").

(3) Relator bases his allegations in paragraph 46 only "upon information and belief" which is insufficient to meet his 9(b) obligations. *See, e.g., United States v. Epic Healthcare Mgmt. Grp.*, 1998 U.S. Dist. LEXIS 10685, at *6-7 (S.D. Tex. Mar. 31, 1998); and *Ricupito v. Indianapolis Life Ins. Co.*, 2010 U.S. Dist. LEXIS 104893, at *15-16 (N.D. Tex. Sep. 30, 2010). As described in in *Epic Healthcare Mgmt. Grp.* and *Ricupito*, Relator can only satisfy his 9(b) obligations by pleading upon information and belief when (1) "the facts constituting fraud are particularly within the adverse party's knowledge or are otherwise inaccessible to the pleader," and (2) "the pleader identifies the available information on which the allegation of fraud is founded, as well as the efforts made to obtain additional information." *Epic Healthcare Mgmt. Grp.*, 1998 U.S. Dist. LEXIS 10685, at *6-7. Relator has established neither in this case. His allegations are comparable to those in *Ricupito* where the court held:

> Although this leeway allows for limited pleading upon information and belief, it "must not be mistaken for license to base claims of fraud on speculation and conclusory allegations." *U.S. ex rel Willard v. Humana Health Plan of Tex.,* 336 F.3d 375, 385 (5th Cir. 2003) (citing *ABC Arbitrage*, 291 F.3d at 350 n.67). Where fraud allegations are premised upon information and belief, the "complaint must set forth a factual basis for such belief." Id. Otherwise, the claimants should clarify that they did not have access

> to the fraud-related facts. *U.S. ex. rel Doe v. Dow Chemical Co.*, 343 F.3d 325, 330 (5th Cir. 2003). Plaintiffs have not alleged that certain facts were in [Defendant's] exclusive knowledge. To the contrary, the current pleadings leave the impression that many allegations plead upon information and belief are within Plaintiffs' knowledge. In sum, the Court finds that the allegations of misrepresentations and omissions by [Defendant] fail to satisfy 9(b)'s particularity requirement ….

2010 U.S. Dist. LEXIS 104893, at *15-16.

Similarly, Relator now lists 274 entities and again concludes "upon information and belief" with no further factual support or description that these entities were "used by, operated by, operated with, in partnership with, and participating in the fraudulent schemes as set forth herein …." Amended Complaint at ¶ 46. It is insufficient for Relator to simply assert based on information and belief that these entities participated in a fraudulent scheme in some unspecified way.

Relator alleges generally that "Next Health encouraged medical providers to utilize and pre-authorize other medical providers." Amended Complaint at ¶ 49. He also generally alleges that these other medical providers "were often not properly qualified, credentialed, or appropriately licensed to order certain medications for patients, and did so unlawfully." *Id.* at 51. However, not only does Relator fail to identify a single "Sub-Level Provider," he also fails to identify any specific regulatory basis on which the alleged delegation would be prohibited. He does not identify either the allegedly required credentials or the allegedly actual and deficient ones. He merely states without support that Next Health encouraged some delegation to some unidentified person that was improper because it violated some unidentified rule. Relator does not cite applicable Texas law because it does not support his position. In fact, pursuant to Tex. Occ. Code § 157.011(b),

Physicians have broad discretion to delegate prescriptive authority.[4] Relator entirely fails to allege noncompliance with this section or any other specific regulation.

Relator's final substantive addition to the Amended Complaint is Exhibit 2, which is largely inscrutable. It is presented with almost no context, and Relator's limited description of the Exhibit is incomplete and/or inaccurate for each of the subparts.

Relator describes Exhibit 2A as "RANDOMLY SELECTED SPREAD SHEETS SHOWING RECORDS OF PRESCRIPTIONS, PLAN PAYORS, AND THE PHARMACIES USED TO FILL THE PRESCRIPTIONS." Amended Complaint, Exhibit 2. We note that the pages attached as Exhibit 2A have only two columns, not three, and that the only page with column headings does not match the description provided by Relator.

Relator describes Exhibit 2B as "RANDOMLY SELECTED SPREAD SHEETS THAT SHOWS THE BENEFICIARIES AND COSTS OF DRUGS." Amended Complaint, Exhibit 2. The attached pages have four untitled columns, one of which is redacted. It is not clear how the three columns correspond, if at all, to Relator's description.

Relator describes Exhibit 2C as "RANDOMLY SELECTED SHOWING ACCOUNTS RECEIVABLE FOR PRESCRIPTIONS WITH PHARMACY ID." Amended Complaint, Exhibit 2. The spreadsheet has seven untitled columns. There is no indication that any of these entries have any relation to any federal claim.

[4] Tex. Occ. Code § 157.011(b) Except as provided by Subsection (b-1), a physician may delegate the prescribing or ordering of a controlled substance only if:

(1) the prescription is for a controlled substance listed in Schedule III, IV, or V as established by the commissioner of the Department of State Health Services under Chapter 481, Health and Safety Code;
(2) the prescription, including a refill of the prescription, is for a period not to exceed 90 days;
(3) with regard to the refill of a prescription, the refill is authorized after consultation with the delegating physician and the consultation is noted in the patient's chart; and
(4) with regard to a prescription for a child less than two years of age, the prescription is made after consultation with the delegating physician and the consultation is noted in the patient's chart.

Ultimately, the Amended Complaint still leaves the critical elements of Relator's claims unalleged. As just a few examples, it cannot be determined from the Amended Complaint:

- Whether the named individuals actually referred any GHP business to any pharmacy.
- If GHP referrals did occur, what pharmacy or pharmacies received the referrals from those individuals and submitted claims to a GHP.
- What financial relationship, if any, the unidentified pharmacies had with Next Health and/or the identified individuals or why those relationships are prohibited under the AKS.
- The identity of the "Federal or State Regulations prohibiting such substitutions" as Next Health allegedly made in paragraph 47.
- What regulation, if any, the Blanket Agreements allegedly violate.
- The identity of any alleged Sub-Level Provider or any specific pharmacy such provider allegedly made referrals to.
- What regulation, if any, the Sub-Level Provider prescribing practices alleged in paragraphs 50 and 51 allegedly violates.
- The nature of the participation in the alleged scheme of any of the 274 entities identified in paragraph 46 beyond the sweeping and conclusory allegation that they were "used by, operated by, operated with, in partnership with, and participating in the fraudulent schemes as set forth herein."

IV. Dismissal Should be With Prejudice

Leave to amend is not automatic, but rather "is within the sound discretion of the district court." *U.S. ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 329 (5th Cir. 2003) (citation omitted). Relator will be unable to cure the deficiencies of his Complaint. Leave to amend may be appropriately denied when amendment would be futile. *See U.S. ex rel. Willard v. Humana Health*

Plan of Texas Inc., 336 F.3d 375, 387 (5th Cir. 2003) (The district court's denial of leave to file an amended complaint was not an abuse of discretion.).

V. Conclusion

Defendant Next Health respectfully requests that this Court grant this Motion in its entirety and, for the reasons discussed herein, dismiss with prejudice all claims asserted against it in Relator's Complaint. Next Health also requests that this Court grant all other and further relief to which it may be justly entitled.

Dated: February 3, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record and/or parties on February 3, 2022 pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Michael Elliott